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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,882	12/19/2001	Sheldon Tobe	PT-1949001	8815

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EXAMINER	
PAK, JOHN D	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/020,882	TOBE, SHELDON	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,21 and 24* is/are pending in the application.

4a) Of the above claim(s) *2-8,11-13,15,16 and 18* is/are withdrawn from consideration.

5)☒ Claim(s) *24* is/are allowed.

6)☒ Claim(s) *1,9,10,14,17,19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/5/2006 has been entered.

Claims 1-19, 21 and 24 are pending in this application.

Pursuant to the restriction requirement of record, claims 2-8, 11-13 and 15-16 stand withdrawn as being directed to non-elected subject matter.
Amended claim 18 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 18 has been amended to delete the "calcium free" feature. All other claims being examined recite both the calcium free and low bicarbonate features.

Distinctness of a dialysis concentrate that is calcium free and low bicarbonate over a dialysis concentrate that is merely low bicarbonate is in evidence from applicant's specification. Applicant discloses that a bicarbonate-containing dialysis solution has precipitation concerns when calcium is present (page 2, lines 26-31). Prior art has addressed this problem by separating the calcium from bicarbonate (page 4, lines 5-8). Applicant states, "there exists a need for a sterile calcium-free low bicarbonate concentrate for quickly and easily preparing dialysate solutions ..." (page 7, lines 2-3).

Clearly, a dialysis concentrate that is calcium free and low bicarbonate is distinct over a dialysis concentrate that reads on open amounts of calcium.

There would be undue burden in having to separately search a calcium-containing dialysis concentrate that reads on claim 18. Even though the two inventions share the same or similar classification, each invention is shown to have formed a separate subject for inventive effort, because applicant's own specification establishes a recognition of separate inventive effort and status. A search in the dialysis concentrate or solution art is an extremely challenging and burdensome one because there is no way to efficiently search for the various features that define the invention. Virtually all dialysis concentrate or solution prior art contain some discussion of various electrolytes, which makes it difficult to eliminate false hits; and numerical search of inventive concentration range is next to impossible without reading each reference line by line.

Thus, given the separate subject for inventive effort that gives rise to the unduly burdensome search, and taken with the distinctness of the invention of claim 18 over that of the previously examined claims that were finally rejected, the restriction requirement claim 18 and said claims is deemed to be proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits (note, applicant cannot shift the elected invention in an RCE).

Accordingly, claim 18 is additionally withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims **1, 9-10, 14, 17, 19, 21** and **24** will presently be examined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9-10, 14, 17, 19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 1, 14, 17, 18 and 19 have been amended to seemingly require the diluted dialysis concentrate to provide an effective in vivo bicarbonate concentration of 5-27.5 mmol/l. This is a significant deviation from the originally described 5-27.5 mmol/l range. Applicant originally disclosed that the dialysis solution contains 5-27.5 mmol/l (specification page 7):

> minimized. The low bicarbonate sterile solution of the invention typically contains a bicarbonate concentration within the range of 5-30 mmol/l, preferably between 20-30 mmol/l, and more preferably 25 ± 2.5 mmol/l. The solutions with bicarbonate concentrations below 25 mmol/L may have sodium citrate added to them up to 20 mmol/L to act as an anticoagulant.

Given that normal bicarbonate concentration in the blood is in the range of about 22-29 mmol/l, providing in vivo bicarbonate concentration of 5 mmol/l in CRRT would not be desirable, to say the least. Applicant did not specifically disclose such a dangerous protocol, and the originally filed disclosure would not have reasonably conveyed to one skilled in the art such a dangerous protocol.

The amended subject matter is therefore new matter, which does not find adequate descriptive support from the originally filed disclosure. Dependent claims are included here because they do not cure the deficiency of the base claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9-10, 14, 17, 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 14, 17, 18 and 19 have been amended to seemingly require the diluted dialysis concentrate to provide an effective in vivo bicarbonate concentration of 5-27.5 mmol/l. However, applicant's claim language is unclear and indefinite, and the Examiner is uncertain of applicant's exact claim scope.

The issue with claim 1 is discussed below for illustration of the same or analogous indefiniteness problems in all other claims:

1. (currently amended) A sterile calcium free low bicarbonate dialysis concentrate composition for continuous renal replacement therapy for use in the preparation of a dialysis solution comprising sodium chloride (NaCl), magnesium chloride (MgCl2), and a concentration of sodium bicarbonate (NaHCO3) sufficiently low so as to allow preparation of a sterile dialysis solution for continuous renal replacement therapy having a an effective in vivo bicarbonate concentration of 5-27.5 mmol/l.

It is unclear whether the phrase "having an effective in vivo ..." is supposed to modify "solution" or "therapy." Additionally, if it were the case that the "solution" is to be modified by said phrase, there would be indefiniteness issues raised because it is confusing to state that the dialysis solution itself has an in vivo concentration of one component.

Remaining independent claims are included here for the same or analogous reasons. Dependent claims are included here because they do not cure the deficiency of the base claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 14, 17, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaye et al. (Clinical Nephrology, Vol. 31(3), pp. 132-38, cited and submitted by applicant in the IDS of 4/16/2002).

Kay et al. explicitly disclose a sterile, calcium free dialysate concentrate, which contains 84.57 g/l sodium chloride, 37.77 g/l sodium bicarbonate, and 2.14 g/l magnesium chloride hexahydrate (page 132, left column, see "Methods"). The following is a table of concentration values based on Kay's disclosure:

	Bicarbonate	Sodium	Chloride	Magnesium
No dilution	450 mM	1900 mM	1470 mM	10.5 mM
Table 1 on page 133	34.5 ± 0.3 mM	142.3 ±1 mM	108.2 ± 1.1 mM	0.85 ± 0.01 mM
17 X dilution (not expressly disclosed; based only on calculation)	26.5 mM	112 mM	86.5 mM	0.6 mM

Instant claims are directed to a concentrate, for use in the preparation of a dialysis solution. Although the claims are confusing and indefinite for reasons discussed earlier, one alternative interpretation is that the claims require that the dialysis solution provide for an in vivo bicarbonate concentration of 5-27.5 mM. Note, under this interpretation, the actual bicarbonate concentration in the dialysis solution could be higher than 5-27.5 mM since renal failure often results in high blood acidity. To achieve an in vivo bicarbonate concentration of 5-27.5 mM for a patient suffering from high blood acidity, the dialysis solution would have to contain higher amounts of bicarbonate than 5-27.5 mM.

Therefore, Kay's dialysate concentrate meets the instant claims. The claims are thereby anticipated.

Claim 24 is allowed. Applicant is advised that because the entire application cannot be allowed at this time, claim 24 will have to undergo a search update and review at the time of the next Office action.

Applicant is further advised that grounds of rejection outstanding from the previous Office action over Purcell et al. (35 USC 102) and Martis et al. in view of Purcell et al. (35 USC 103) are withdrawn in view of applicant's "an effective in vivo" bicarbonate concentration amendatory feature. If in response to this Office action applicant deletes this amendatory feature, applicant is advised that reinstatement of those grounds of rejection may be possible, and such reinstatement will be considered necessitated by applicant's amendment, wherein the action can be made FINAL. At this time, the Examiner cannot comment on grounds of rejection, which cannot be applied against the present claims. The new declaration by Dr. Tobe is therefore moot.

As for the submitted information regarding Normocarb, the Examiner finds such information of little worth. The basic issue is that the Examiner is trying to find out whether a Normocarb product reading on the instant claims was in existence, in public

use, disclosed publicly and/or otherwise involved in commercial activity before 12/20/1999. Applicant's submitted information with the filing of the RCE totally fails to shed any light on this matter. It is so noted for the record for anyone reviewing this prosecution history.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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